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STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2017

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A N A C T

RELATING TO INSURANCE

Introduced By: Representatives Blazejewski, Solomon, Barros, McKiernan, and
O'Brien

Date Introduced: March 01, 2017

Referred To: House Corporations

It is enacted by the General Assembly as follows:

1 SECTION 1. Chapter 27-18 of the General Laws entitled "Accident and Sickness
2 Insurance Policies" is hereby amended by adding thereto the following section:

3 **27-18-83. Step therapy protocol.**

4 (a) As used in this section the following words shall, unless the context clearly requires
5 otherwise, have the following meanings:

6 (1) "Clinical practice guidelines" means a systematically developed statement to assist
7 practitioner and patient decisions about appropriate health care for specific clinical circumstances.

8 (2) "Clinical review criteria" means the written screening procedures, decision abstracts,
9 clinical protocols and practice guidelines used by an insurer, health plan, or utilization review
10 organization to determine the medical necessity and appropriateness of health care services.

11 (3) "Step therapy protocol" means a protocol or program that establishes the specific
12 sequence in which prescription drugs for a specified medical condition that are medically
13 appropriate for a particular patient and are covered as a pharmacy or medical benefit, including
14 self-administered and physician-administered drugs, are covered by an insurer or health plan.

15 (4) "Step therapy override determination" means a determination as to whether step
16 therapy should apply in a particular situation, or whether the step therapy protocol should be
17 overridden in favor of immediate coverage of the patient's and/or prescriber's preferred drug. This
18 determination is based on a review of the patient's and/or prescriber's request for an override,
19 along with supporting rationale and documentation.

1 (5) "Utilization review organization" means an entity that conducts utilization review,
2 other than a health carrier performing utilization review for its own health benefit plans.

3 (b) Any policy, contract, agreement, plan or certificate of insurance issued, delivered or
4 renewed within the state that provides coverage for prescription drugs and uses step therapy
5 protocols shall have the following requirements and restrictions:

6 (1) Clinical review criteria used to establish step therapy protocols shall be based on
7 clinical practice guidelines:

8 (i) Independently developed by a multidisciplinary panel with expertise in the medical
9 condition, or conditions, for which coverage decisions said criteria will be applied; and

10 (ii) That recommend drugs be taken in the specific sequence required by the step therapy
11 protocol.

12 (c) When coverage of medications for the treatment of any medical condition are
13 restricted for use by an insurer, health plan, or utilization review organization via a step therapy
14 protocol, the patient and prescribing practitioner shall have access to a clear and convenient
15 process to request a step therapy exception determination. An insurer, health plan, or utilization
16 review organization may use its existing medical exceptions process to satisfy this requirement.
17 The process shall be disclosed to the patient and health care providers, including documenting
18 and making easily accessible on the insurer's, health plan's or utilization review organization's
19 website.

20 (d) A step therapy override exception determination request shall be expeditiously
21 granted if:

22 (1) The required drug is contraindicated or will likely cause an adverse reaction by or
23 physical or mental harm to the patient;

24 (2) The required drug is expected to be ineffective based on the known relevant physical
25 or mental characteristics of the insured and the known characteristics of the drug regimen;

26 (3) The enrollee has tried the step therapy-required drug while under their current or a
27 previous health plan, or another drug in the same pharmacologic class or with the same
28 mechanism of action and such drugs were discontinued due to lack of efficacy or effectiveness,
29 diminished effect, or an adverse event;

30 (4) The patient is stable on a drug recommended by their health care provider for the
31 medical condition under consideration while on a current or previous health insurance or health
32 benefit plan;

33 (5) The step therapy-required drug is not in the best interest of the patient, based on
34 medical appropriateness.

1 (e) Upon the granting of a step therapy override exception request, the insurer, health
2 plan, utilization review organization, or other entity shall authorize dispensation of and coverage
3 for the drug prescribed by the enrollee's treating health care provider, provided such drug is a
4 covered drug under such policy or contract.

5 (f) This section shall not be construed to prevent:

6 (1) An insurer, health plan, or utilization review organization from requiring an enrollee
7 try an AB-rated generic equivalent prior to providing reimbursement for the equivalent branded
8 drug;

9 (2) A health care provider from prescribing a drug they determine is medically
10 appropriate.

11 SECTION 2. Chapter 27-19 of the General Laws entitled "Nonprofit Hospital Service
12 Corporations" is hereby amended by adding thereto the following section:

13 **27-19-74. Step therapy protocol.**

14 (a) As used in this section the following words shall, unless the context clearly requires
15 otherwise, have the following meanings:

16 (1) "Clinical practice guidelines" means a systematically developed statement to assist
17 practitioner and patient decisions about appropriate health care for specific clinical circumstances.

18 (2) "Clinical review criteria" means the written screening procedures, decision abstracts,
19 clinical protocols and practice guidelines used by an insurer, health plan, or utilization review
20 organization to determine the medical necessity and appropriateness of health care services.

21 (3) "Step therapy protocol" means a protocol or program that establishes the specific
22 sequence in which prescription drugs for a specified medical condition that are medically
23 appropriate for a particular patient and are covered as a pharmacy or medical benefit, including
24 self-administered and physician-administered drugs, are covered by an insurer or health plan.

25 (4) "Step therapy override determination" means a determination as to whether step
26 therapy should apply in a particular situation, or whether the step therapy protocol should be
27 overridden in favor of immediate coverage of the patient's and/or prescriber's preferred drug. This
28 determination is based on a review of the patient's and/or prescriber's request for an override,
29 along with supporting rationale and documentation.

30 (5) "Utilization review organization" means an entity that conducts utilization review,
31 other than a health carrier performing utilization review for its own health benefit plans.

32 (b) Any policy, contract, agreement, plan or certificate of insurance issued, delivered or
33 renewed within the state that provides coverage for prescription drugs and uses step therapy
34 protocols shall have the following requirements and restrictions:

1 (1) Clinical review criteria used to establish step therapy protocols shall be based on
2 clinical practice guidelines:

3 (i) Independently developed by a multidisciplinary panel with expertise in the medical
4 condition, or conditions, for which coverage decisions said criteria will be applied; and

5 (ii) That recommend drugs be taken in the specific sequence required by the step therapy
6 protocol.

7 (c) When coverage of medications for the treatment of any medical condition are
8 restricted for use by an insurer, health plan, or utilization review organization via a step therapy
9 protocol, the patient and prescribing practitioner shall have access to a clear and convenient
10 process to request a step therapy exception determination. An insurer, health plan, or utilization
11 review organization may use its existing medical exceptions process to satisfy this requirement.
12 The process shall be disclosed to the patient and health care providers, including documenting
13 and making easily accessible on the insurer's, health plan's or utilization review organization's
14 website.

15 (d) A step therapy override exception determination request shall be expeditiously
16 granted if:

17 (1) The required drug is contraindicated or will likely cause an adverse reaction by or
18 physical or mental harm to the patient;

19 (2) The required drug is expected to be ineffective based on the known relevant physical
20 or mental characteristics of the insured and the known characteristics of the drug regimen;

21 (3) The enrollee has tried the step therapy-required drug while under their current or a
22 previous health plan, or another drug in the same pharmacologic class or with the same
23 mechanism of action and such drugs were discontinued due to lack of efficacy or effectiveness,
24 diminished effect, or an adverse event;

25 (4) The patient is stable on a drug recommended by their health care provider for the
26 medical condition under consideration while on a current or previous health insurance or health
27 benefit plan;

28 (5) The step therapy-required drug is not in the best interest of the patient, based on
29 medical appropriateness.

30 (e) Upon the granting of a step therapy override exception request, the insurer, health
31 plan, utilization review organization, or other entity shall authorize dispensation of and coverage
32 for the drug prescribed by the enrollee's treating health care provider, provided such drug is a
33 covered drug under such policy or contract.

34 (f) This section shall not be construed to prevent:

1 (1) An insurer, health plan, or utilization review organization from requiring an enrollee
2 try an AB-rated generic equivalent prior to providing reimbursement for the equivalent branded
3 drug;

4 (2) A health care provider from prescribing a drug they determine is medically
5 appropriate.

6 SECTION 3. Chapter 27-20 of the General Laws entitled "Nonprofit Medical Service
7 Corporations" is hereby amended by adding thereto the following section:

8 **27-20-70. Step therapy protocol.**

9 (a) As used in this section the following words shall, unless the context clearly requires
10 otherwise, have the following meanings:

11 (1) "Clinical practice guidelines" means a systematically developed statement to assist
12 practitioner and patient decisions about appropriate health care for specific clinical circumstances.

13 (2) "Clinical review criteria" means the written screening procedures, decision abstracts,
14 clinical protocols and practice guidelines used by an insurer, health plan, or utilization review
15 organization to determine the medical necessity and appropriateness of health care services.

16 (3) "Step therapy protocol" means a protocol or program that establishes the specific
17 sequence in which prescription drugs for a specified medical condition that are medically
18 appropriate for a particular patient and are covered as a pharmacy or medical benefit, including
19 self-administered and physician-administered drugs, are covered by an insurer or health plan.

20 (4) "Step therapy override determination" means a determination as to whether step
21 therapy should apply in a particular situation, or whether the step therapy protocol should be
22 overridden in favor of immediate coverage of the patient's and/or prescriber's preferred drug. This
23 determination is based on a review of the patient's and/or prescriber's request for an override,
24 along with supporting rationale and documentation.

25 (5) "Utilization review organization" means an entity that conducts utilization review,
26 other than a health carrier performing utilization review for its own health benefit plans.

27 (b) Any policy, contract, agreement, plan or certificate of insurance issued, delivered or
28 renewed within the state that provides coverage for prescription drugs and uses step therapy
29 protocols shall have the following requirements and restrictions:

30 (1) Clinical review criteria used to establish step therapy protocols shall be based on
31 clinical practice guidelines:

32 (i) Independently developed by a multidisciplinary panel with expertise in the medical
33 condition, or conditions, for which coverage decisions said criteria will be applied; and

34 (ii) That recommend drugs be taken in the specific sequence required by the step therapy

1 protocol.

2 (c) When coverage of medications for the treatment of any medical condition are
3 restricted for use by an insurer, health plan, or utilization review organization via a step therapy
4 protocol, the patient and prescribing practitioner shall have access to a clear and convenient
5 process to request a step therapy exception determination. An insurer, health plan, or utilization
6 review organization may use its existing medical exceptions process to satisfy this requirement.
7 The process shall be disclosed to the patient and health care providers, including documenting
8 and making easily accessible on the insurer's, health plan's or utilization review organization's
9 website.

10 (d) A step therapy override exception determination request shall be expeditiously
11 granted if:

12 (1) The required drug is contraindicated or will likely cause an adverse reaction by or
13 physical or mental harm to the patient;

14 (2) The required drug is expected to be ineffective based on the known relevant physical
15 or mental characteristics of the insured and the known characteristics of the drug regimen;

16 (3) The enrollee has tried the step therapy-required drug while under their current or a
17 previous health plan, or another drug in the same pharmacologic class or with the same
18 mechanism of action and such drugs were discontinued due to lack of efficacy or effectiveness,
19 diminished effect, or an adverse event;

20 (4) The patient is stable on a drug recommended by their health care provider for the
21 medical condition under consideration while on a current or previous health insurance or health
22 benefit plan;

23 (5) The step therapy-required drug is not in the best interest of the patient, based on
24 medical appropriateness.

25 (e) Upon the granting of a step therapy override exception Request, the insurer, health
26 plan, utilization review organization, or other entity shall authorize dispensation of and coverage
27 for the drug prescribed by the enrollee's treating health care provider, provided such drug is a
28 covered drug under such policy or contract.

29 (f) This section shall not be construed to prevent:

30 (1) An insurer, health plan, or utilization review organization from requiring an enrollee
31 try an AB-rated generic equivalent prior to providing reimbursement for the equivalent branded
32 drug;

33 (2) A health care provider from prescribing a drug they determine is medically
34 appropriate.

1 SECTION 4. Chapter 27-41 of the General Laws entitled "Health Maintenance
2 Organizations" is hereby amended by adding thereto the following section:

3 **27-41-87. Step therapy protocol.**

4 (a) As used in this section the following words shall, unless the context clearly requires
5 otherwise, have the following meanings:

6 (1) "Clinical practice guidelines" means a systematically developed statement to assist
7 practitioner and patient decisions about appropriate health care for specific clinical circumstances.

8 (2) "Clinical review criteria" means the written screening procedures, decision abstracts,
9 clinical protocols and practice guidelines used by an insurer, health plan, or utilization review
10 organization to determine the medical necessity and appropriateness of health care services.

11 (3) "Step therapy protocol" means a protocol or program that establishes the specific
12 sequence in which prescription drugs for a specified medical condition that are medically
13 appropriate for a particular patient and are covered as a pharmacy or medical benefit, including
14 self-administered and physician-administered drugs, are covered by an insurer or health plan.

15 (4) "Step therapy override determination" means a determination as to whether step
16 therapy should apply in a particular situation, or whether the step therapy protocol should be
17 overridden in favor of immediate coverage of the patient's and/or prescriber's preferred drug. This
18 determination is based on a review of the patient's and/or prescriber's request for an override,
19 along with supporting rationale and documentation.

20 (5) "Utilization review organization" means an entity that conducts utilization review,
21 other than a health carrier performing utilization review for its own health benefit plans.

22 (b) Any policy, contract, agreement, plan or certificate of insurance issued, delivered or
23 renewed within the state that provides coverage for prescription drugs and uses step therapy
24 protocols shall have the following requirements and restrictions:

25 (1) Clinical review criteria used to establish step therapy protocols shall be based on
26 clinical practice guidelines:

27 (i) Independently developed by a multidisciplinary panel with expertise in the medical
28 condition, or conditions, for which coverage decisions said criteria will be applied; and

29 (ii) That recommend drugs be taken in the specific sequence required by the step therapy
30 protocol.

31 (c) When coverage of medications for the treatment of any medical condition are
32 restricted for use by an insurer, health plan, or utilization review organization via a step therapy
33 protocol, the patient and prescribing practitioner shall have access to a clear and convenient
34 process to request a step therapy exception determination. An insurer, health plan, or utilization

1 review organization may use its existing medical exceptions process to satisfy this requirement.
2 The process shall be disclosed to the patient and health care providers, including documenting
3 and making easily accessible on the insurer's, health plan's or utilization review organization's
4 website.

5 (d) A step therapy override exception determination request shall be expeditiously
6 granted if:

7 (1) The required drug is contraindicated or will likely cause an adverse reaction by or
8 physical or mental harm to the patient;

9 (2) The required drug is expected to be ineffective based on the known relevant physical
10 or mental characteristics of the insured and the known characteristics of the drug regimen;

11 (3) The enrollee has tried the step therapy-required drug while under their current or a
12 previous health plan, or another drug in the same pharmacologic class or with the same
13 mechanism of action and such drugs were discontinued due to lack of efficacy or effectiveness,
14 diminished effect, or an adverse event;

15 (4) The patient is stable on a drug recommended by their health care provider for the
16 medical condition under consideration while on a current or previous health insurance or health
17 benefit plan;

18 (5) The step therapy-required drug is not in the best interest of the patient, based on
19 medical appropriateness.

20 (e) Upon the granting of a step therapy override exception Request, the insurer, health
21 plan, utilization review organization, or other entity shall authorize dispensation of and coverage
22 for the drug prescribed by the enrollee's treating health care provider, provided such drug is a
23 covered drug under such policy or contract.

24 (f) This section shall not be construed to prevent:

25 (1) An insurer, health plan, or utilization review organization from requiring an enrollee
26 try an AB-rated generic equivalent prior to providing reimbursement for the equivalent branded
27 drug;

28 (2) A health care provider from prescribing a drug they determine is medically
29 appropriate.

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1 SECTION 5. This act shall take effect upon passage and shall apply only to health
2 insurance and health benefit plans delivered, issued for delivery, or renewed on or after January 1,
3 2018.

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EXPLANATION
BY THE LEGISLATIVE COUNCIL
OF
A N A C T
RELATING TO INSURANCE

1 This act would require health insurers, nonprofit hospital service corporations, nonprofit
2 medical service corporations and health maintenance organizations that issue policies that provide
3 coverage for prescription drugs and use step therapy protocols, to base step therapy protocols on
4 appropriate clinical practice guidelines or published peer review data developed by independent
5 experts with knowledge of the condition or conditions under consideration; that patients be
6 exempt from step therapy protocols when inappropriate or otherwise not in the best interest of the
7 patients; and that patients have access to a fair, transparent and independent process for
8 requesting an exception to a step therapy protocol when the patients physician deems appropriate.

9 This act would take effect upon passage and would apply only to health insurance and
10 health benefit plans delivered, issued for delivery, or renewed on or after January 1, 2018.

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